

K132527
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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number: _____

1. **Date of submission:** August 07, 2013

NOV 14 2013

2. **Submitter**

SonoScape Company Limited

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3. **Proposed Device Identification**

Trade/Proprietary Name: S30 Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System and Transducers

Classification:

21 FR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 FR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Classification Panel: Radiology

Device Class: II

4. **Legally Marketed Predicate Device**

SonoScape Company Limited, Diagnostic Ultrasound System, Model SSI-8000 has been cleared by FDA through 510(k) No.K102642 (Decision Date – March 04, 2011).

5. Device Description

The SonoScape S30 Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

6. Intended Use Statement

The SonoScape S30 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.

7. Testing

Laboratory testing was conducted to verify that the S30 system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output

Measurement Standard for Diagnostic Ultrasound Equipment" and "NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment".

IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

IEC 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

8. Clinical Test:

No clinical testing was required.

9. Comparison Table

The differences between the S30 and the predicate device SSI-8000 in almost every part are listed in the tables below.

Table 1 Intended Use Comparison

ID	Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
1	Intended Use	The SonoScape S30 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal,	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal,	Same

		Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.	Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.	
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Table 2 General Comparison

ID	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
2	Classification Name	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Same
3	Product Code	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	Same
4	Regulation Number	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	Same
5	Panel	Radiology	Radiology	Same
6	Class	II	II	Same
7	Probe Type & Connectors	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz L752 Linear Array, 5.0-12.0 MHz 10L1 Linear Array, 6.0-12.0 MHz C362 Curved Array, 2.0-6.0 MHz C344 Curved Array, 2.0-5.0 MHz C353 Curved Array, 2.0-6.0 MHz C542 Curved Array, 2.0-7.0 MHz C322 Curved Array, 2.0-6.0 MHz C353 Curved Array, 2.0-6.0 MHz	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz C362 Curved Array, 2.0-6.0 MHz C344 Curved Array, 2.0-5.0 MHz	SE Analysis 1

ID	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
		MHz		
		C611 Micro-curved Array, 4.0-8.0 MHz C311 Micro-curved Array, 2.0-4.0 MHz	C611 Micro-curved Array, 4.0-8.0 MHz	
		VC6-2 Curved Array, 2.0-6.0 MHz	VC6-2 Curved Array, 2.0-6.0 MHz	
		6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz BCC9-5 Micro-convex Array 5.0-9.0MHz BCL10-5 Micro-convex Array 5.0-10.0MHz	6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz	
		2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz	2P1 Phased Array, 2.0-4.0 MHz 5P1 Phased Array, 4.0-7.0 MHz	
		MPTEE Multi-plane Array, 4.0-7.0 MHz MPTEE mini Multi-plane Array, 4.0-7.0 MHz	MPTEE Multi-plane Array, 4.0-7.0 MHz MPTEE mini Multi-plane Array, 4.0-7.0 MHz	
		Multi-port connector connects 4 transducers	Multi-port connector connects 4 transducers	Same
8	Acoustic Track	TRACK 3	TRACK 3	Same

Table 3 Functions Comparison

ID	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
9	Design	Based on an embedded Linux operating system.	Based on an embedded Linux operating system.	Same
		Based on a 64 channel full digital beam former.	Based on a 64 channel full digital beam former.	SE
		Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	Same
		Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Same
		Cine play back capability	Cine play back capability	Same
		Image file archive	Image file archive	Same
		Software upgrade with USB flash drive.	Software upgrade with USB flash drive.	Same
		Digital Scan Converter 800×600	Digital Scan Converter 800×600	Same
		With touch panel	With full keyboard	SE Analysis 2
10	Operation Controls	TGC 8 slider	TGC 8 slider	Same
		Depth Range: 3 to 32 cm	Depth Range: 3 to 32 cm	Same
		Image sector size: 32 lines to full B (512 lines)	Image sector size: 32 lines to full B (256 lines)	SE Analysis 3
		Image Sector position: Steering within full maximum	Image Sector position: Steering within full maximum	Same
		B orientation flip :L/R key with marking on the screen	B orientation flip :L/R key with marking on the screen	Same
		B Dynamic range control: preset 14 curves over 140 dB	B Dynamic range control: preset 14 curves over 140 dB	Same
		Gray Scale Control: 7 Settings	Gray Scale Control: 7 Settings	Same
		Focal Number: 12 focal zone setting	Focal Number: 9 focal zone setting	SE Analysis 3
		B persistence: 0-95%	B persistence: 0-95%	Same
		Image Processing: Smoothing, edge enhancement	Image Processing: Smoothing, edge enhancement	Same
		PW sweeping speed 2,4,6,8 sec over display	PW sweeping speed 2,4,6,8 sec over display	Same
		PW Wall filter setting: 16 settings, 25 to 750 HZ	PW Wall filter setting: 16 settings, 25 to 750 HZ	Same

ID	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
		PW sample volume:0.5 to 20mm	PW sample volume:0.5 to 20mm	Same
		PW/B update: with UPDATE key	PW/B update: with UPDATE key	Same
		PW cursor steering: Steer soft key	PW cursor steering: Steer soft key	Same
		PW angle correction:0 to 80 degree user control	PW angle correction:0 to 72 degree user control	SE Analysis 3
		PW trace: Peak, Mean	PW trace: Peak, Mean	
		PW spectrum dynamic range:10 preset curve over 15-48 dB	PW spectrum dynamic range:10 preset curve over 15-48 dB	Same
		Spectrum baseline shift and invert	Spectrum baseline shift and invert	Same
		Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	Same
		Color steering on flat probe:±20, ±16,0	Color steering on flat probe:±20, ±16, 0	Same
		Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Color Wall Filter: Color wall filter with 16 selection,25-750 of PRF	Same
		Color priority-B priority soft menu	Color priority-B priority soft menu	Same
		Color Packet size: preset per Exam, horizontal, vertical, off	Color Packet size: preset per Exam, horizontal, vertical, off	Same
		Zoom adjustable	Zoom adjustable	Same
		Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	Same
		Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	Same
11	Operation Mode	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	Same
12	Display Modes	Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and	Dual B, Quad Display, B and M, B and Doppler B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and	Same

ID	Comparison Items	Proposed Device SonoScape S30	Predicate Device SonoScape SSI-8000	Remark
		PW/CW,B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	PW/CW,B,THI and Color M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	
13	Measurement Items	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Same
14	Cine Loop	Automatic review/ manual review	Automatic review/ manual review	Same
		Review speed can be adjusted	Review speed can be adjust	Same

Table 4 Specifications Comparison

ID	Comparison Items	Proposed Device SonoScape S30			Predicate Device SonoScape SSI-8000			Remark
15	Power Supply	Voltage: 110-127/220-240 VAC			Voltage:100/220VAC			SE Analysis 4
		Frequency: 50/60 Hz			Frequency: 50/60 Hz			
		Power Consumption: 450VA			Power Consumption: 330 VA			
16	Operating Condition	Temperature: 10~40°C			Temperature: 10~40°C			Same
		Relative humidity: 30~75%			Relative humidity: 30~75%			Same
		Air pressure: 700hPa ~1060hPa			Air pressure: 700hPa ~1060hPa			Same
17	Storage Condition	Temperature: -20~55°C			Temperature: -20~55°C			Same
		Relative humidity: 20~90%			Relative humidity: 20~90%			Same
		Air pressure: 700hPa ~1060hPa			Air pressure: 700hPa ~1060hPa			Same
18	Screen Size	19 inch Widescreen LCD monitor			17 inch LCD color monitor			SE Analysis 5
19	Measurement Accuracy	Parameter	Value range	Error range	Parameter	Value range	Error range	
		Display depth	Max 32.9 cm; (Probe depend)	±3%	Display depth	Max 32.9cm; (Probe depend)	±3%	Same
		Distance	0~31.0 cm	±3%	Distance	0~31.0cm	±3%	Same
		Area	Max. ≥855 cm ²	±7%	Area(Trace)	Max. ≥855cm ²	±7%	Same
		Angle	10~193°	±3%	Angle	10°~193° (Probe depend)	±3%	Same

ID	Comparison Items	Proposed Device SonoScape S30			Predicate Device SonoScape SSI-8000			Remark
		Circumference	200 cm	±3%	Circumference	200 cm	±3%	Same
		Volume	Max. 25000 cm ³	±10%	Volume	Max. 25000 cm ³	±10%	Same
		M-Mode time	2,4,6,8 S	±1%	M-Mode time	2, 4, 6, 8 S	±1%	Same
		Heart Rate	8 ~ 1000 beats/sec	±3%	Heart Rate	8 ~ 1000 beats/sec	±3%	Same
		Slope	1300 cm/s	±3%	Slope	1300 cm/s	±3%	Same
		Velocity (PW)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Velocity(pw)	0.04-2940 cm/s	Angle ≤60°, ≤5%	Same
		Velocity (CW)	0.12-3795 cm/s	Angle ≤60°, ≤5%	Velocity(cw)	0.13-3529 cm/s	Angle ≤60°, ≤5%	SE Analysis 6
		Velocity (Color)	1-298 cm/s	Angle ≤60°, ≤5%	Velocity (color)	2-226cm/s	Angle ≤60°, ≤5%	
20	Acoustic Output	Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max			Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm ² maximum. TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm ² max			Same

SE Analysis 1:

Probe Type. Compare to the predicate device, the proposed device is with different probe type or frequency, such as L752, 10L1, C353 etc. But no new intended use is added and all of them comply with IEC 60601-2-37, therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

SE Analysis 2:

The proposed device is with touch panel and the predicate device is with the full keyboard, but both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 3:

The proposed device and the predicate device are with different Image sector size/ Focal number/ PW angle correction, but the proposed device is better. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

SE Analysis 4

The Power Supply of the proposed device and the predicate device are 110-127/220-240 VAC, 450VA and 100/220VAC, 330 VA respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

SE Analysis 5

The screen size of the proposed is larger than that of the SSI-8000. This difference is considered to have no effect on effectiveness and safety.

SE Analysis 6:

The proposed device and the predicate device are with different measurement accuracy in Velocity (CW/ Color), but the proposed device is better. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Discussion of Substantially Equivalent

The subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

10. Substantially Equivalent Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S30 Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2013

SonoScape Company Limited
% Ms Toki Wu
Regulatory Affairs Manager
Yizhe Building, Yuquan Road, Nanshan
Shenzhen, Guangdong
CHINA 518051

Re: K132527

Trade/Device Name: S30 Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 7, 2013
Received: August 19, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers, intended for use with the S30 Digital Color Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P1 Phase Array	5P1 Phase Array	C611 Micro-curved Array
C311 Micro-curved Array	6V1 Micro-curved Array	6V3 Micro-curved Array
EC9-5 Micro-curved Array	BCC9-5 Micro-curved Array	BCL10-5 Biplane Array
C344 Curved Array	C353 Curved Array	C542 Curved Array
C362 Curved Array	C322 Curved Array	VC6-2 Curved Array
L741 Linear Array	L742 Linear Array	L743 Linear Array
L752 Linear Array	10L1 Linear Array	MPTEE Multi-plane Array
MPTEE mini Multi-plane Array		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132527

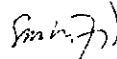
Device Name: S30 Digital Color Doppler Ultrasound System

Indications for Use: The SonoScape S30 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Trans-esoph (Cardiac), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132527

Diagnostic Ultrasound Indications for Use Form

System: SonoScape S30
 Diagnostic Ultrasound Pulsed Echo System
 Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4,5
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
 M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

 (Division Sign Off)
 Division of Radiological Health
 Office of *In Vitro* Diagnostic and Radiological Health

510(k) _____

Indications for Use

7-2

Diagnostic Ultrasound Indications for Use Form

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use: Diagnostic ultrasound imaging of transcranial artery

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CW D	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k) _____

Indications for Use

7-3

Diagnostic Ultrasound Indications for Use Form

Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; **P** = previously cleared by FDA; **E** = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-4

Diagnostic Ultrasound Indications for Use Form

Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-5

Diagnostic Ultrasound Indications for Use Form

Transducer: C311 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3,4
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-6

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-7

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-9

Diagnostic Ultrasound Indications for Use Form

Transducer: BCC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);

M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-10

Diagnostic Ultrasound Indications for Use Form

Transducer: BCL10-5 Biplane Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-11

Diagnostic Ultrasound Indications for Use Form

Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-12

Diagnostic Ultrasound Indications for Use Form

Transducer: C353 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-13

Diagnostic Ultrasound Indications for Use Form

Transducer: C542 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-14

Diagnostic Ultrasound Indications for Use Form

Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power: (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; **P** = previously cleared by FDA; **E** = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-15

Diagnostic Ultrasound Indications for Use Form

Transducer: C322 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal	N	N	N		N	N	Note 1	Notes 2,4
Imaging & Other	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-16

Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD.

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

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Diagnostic Ultrasound Indications for Use Form

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P	P	P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

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Diagnostic Ultrasound Indications for Use Form

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

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Diagnostic Ultrasound Indications for Use Form

Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-20

Diagnostic Ultrasound Indications for Use Form

Transducer: L752 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-21

Diagnostic Ultrasound Indications for Use Form

Transducer: 10L1 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendixNote 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-22

Diagnostic Ultrasound Indications for Use Form

Transducer: MPTEE Multi-plane Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Indications for Use

7-23

Diagnostic Ultrasound Indications for Use Form

Transducer: MPTEE mini Multi-plane Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
Peripheral Vessel	Other (specify)								
	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI (The feature does not use contrast agents);
M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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